Section 11: 510(k) Summary

APR 16 2014

Submitters Name and Address: Currie Medical Specialties, Inc.
8758 Hellman Avenue
Rancho Cucamonga, CA 91730
Phone: (909) 912-0900
Fax: (909) 944-3030

FDA Registration Number: 2023637

Contact Person: Owen J. Bry, Director of Quality Assurance

Date Summary Prepared: 12/17/2013

Trade or Proprietary Name(s): Currie Medical Reprocessed ALP® Calf, Thigh and Foot Compression Sleeves (all sizes)

Common Name: Compression sleeve limb

Product Code: JOW

Panel: Cardiovascular

Regulation Number: 870.5800

Classification: Class II

Predicate Device(s): K955853 – Healthcare Service & Supply Pump ALP 501 System
K964188 – Healthcare Service & Supply PVA (Pneumatic Venous Augmentation) Foot Garment

Device Description:

Currie Medical Specialties (CMS) ALP® reprocessed compression sleeves are compression devices, which when attached to the ALP® 501 Pump System, provide intermittent, sequentially gradient pressure to a patients leg/foot for the prevention of deep vein thrombosis (DVT). When the compression sleeve is inflated, the veins collapse which forces blood to move upward toward the heart. After compression is complete, the sleeves deflate which allows the veins to reopen and bring oxygenated blood to the calf, thigh or foot. The inflation and deflation sequence is predicated by the ALP® 501 Pump System controller.

Intended Use:
The intended use of this device, as well as the predicate device, is to provide external limb compression in order to artificially imitate the pumping action of the leg muscles. This provides muscle contraction required by the venous return system, thereby helping to prevent venous stasis and subsequent thrombosis and embolism. The cyclic and alternating inflation and deflation of the garments closely simulates the normal healthy pumping action of the limb muscles to stimulate deep venous blood flow and the reactivation or increase in the body's fibrinolytic system.

This submission is intended for use of the pump at pressure levels of 40 mm Hg.

Indications for Use:

The Currie Medical Reprocessed ALP® Calf, Thigh and Foot Compression Sleeves (all sizes) are recommended for the use in patients for whom external compression therapy using the ALTERNATING LEG PRESSURE® (ALP®) SYSTEM is indicated to reduce the incidence of deep vein thrombosis and resulting pulmonary embolism due to the presence of risk factors for thrombosis formation.

Technological characteristics of the CMS Reprocessed ALP® Calf, Thigh and Foot Compression Sleeves:

The CMS ALP® Reprocessed Calf, Thigh and Foot Compression Sleeves indications for use, fundamental scientific technology, overall design, materials, energy source, mode of operation, performance characteristics are identical and no different than the predicate device.

Summary of Comparison Tests (Non-Clinical Tests):

Bench testing was conducted to ensure that reprocessing did not compromise the performance or safety and efficacy of the device in a manner that is substantially equivalent to that of the predicate devices (K955853 & K964188).

Bench testing was conducted to demonstrate a bladder leak test where the bladders were pressurized to 3 psi to ensure the bladders did not leak at this pressure and were not affected by reprocessing. A bladder seal pull test was performed, where the bladder seal was pulled apart at > 5 lbs of force to demonstrate the seals were intact and were not affected by reprocessing. A velcro functionality test was performed where bladders were pressurized to 2 psi to determine velcro adhesion remained intact at this pressure and were not affected by reprocessing. Finally, an inflation-deflation time test was performed to demonstrate product integrity remained the same in comparison to the predicate device. This required the devices to be inflated to 40 mm Hg and monitor the pressure over time. The series of data demonstrated that the reprocessing did not affect the performance, or the safety and efficacy of the device.

Biocompatibility

Reprocessing did not affect the biocompatibility of the device.

Conclusion

The Currie Medical Specialties ALP® Reprocessed Calf, Thigh, and Foot Compression Sleeves have demonstrated that they perform as safe and effective as the ALP® non-sterile predicate devices (K955853 & K964188) and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 16, 2014

Currie Medical Specialties, Inc.
Mr. Owen J. Bry
Director of Quality Assurance
8758 Hellman Ave
Rancho Cucamonga, CA 91730

Re: K140092
Trade/Device Name: Currie Medical Reprocessed ALP® Calf, Thigh and Foot Compression Sleeves (all sizes)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: February 18, 2014
Received: February 19, 2014

Dear Mr. Bry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to . http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CURRIE MEDICAL SPECIALTIES, INC.	Reprocessed ALP® Compression Sleeve Device 510(k) Pre-market Notification

INDICATIONS FOR USE

Applicant:	Currie Medical Specialties, Inc.
510(k) Number (if known):	K140092
Device Name:	Currie Medical Reprocessed ALP® Calf, Thigh and Foot Compression Sleeves (all sizes)

Indications for Use:

The Currie Medical Reprocessed ALP® Calf, Thigh and Foot Compression Sleeves (all sizes) are recommended for the use in patients for whom external compression therapy using the ALTERNATING LEG PRESSURE® (ALP®) SYSTEM is indicated to reduce the incidence of deep vein thrombosis and resulting pulmonary embolism due to the presence of risk factors for thrombosis formation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-the-Counter_____
Per 21 CFR 801.109

Bram D. Zuckerman -S
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